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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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TOWNSEND AND TOWNSEND AND CREW LLP
8TH FLOOR
TWO EMBARCADERO CENTER
SAN FRANCISCO, CA 94111

EXAMINER

WALICKA, MALGORZATA A

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,611	Applicant(s) CECH ET AL.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/27, 7/26 and 9/10/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21, 23-26 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) 23-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21 and 35-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/8/03, 1/20/04 & 3/23/04</u> | 6) <input type="checkbox"/> Other: _____ |

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The Amendment filed May 27, 2004 and Supplemental Responses filed July 26 and September 10, 2004 are acknowledged. Filing of formal drawings on July 27 and Information Disclosure Statement of August 23, 2004 is acknowledged. Claims 1- 9, 13-16, 19, 21, 23-28 and 31-32 have been amended; claims 20 and 22 have been cancelled and new claims 35-46 have been added in amendment of May 27, 2004. In the Amendment of September 10, 2004 Applicants amended claims 1, 2, 5- 9, 13-14, 38- 39, 40 and 45- 46, and canceled claims 27-34. Claims 1-19, 21, 23-26 and 35-46 are pending in the application and are the subject of this Office Action.

DETAILED ACTION

1. Restriction/Election

Applicants' request for rejoinder of claims 23-26 has been noticed. Applicants' argue that claim 23 covers "amplification primers for use in the detection method of claim 14".

Applicants' request has been considered. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims that are directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are subject to being rejoined. In the instant case, however, Applicants elected claims directed to a process of using a product and not the product itself, thus the product claims are not subject to being rejoined.

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2. Objections

2.1. Priority

The examiner acknowledges amendment to paragraph [0001] of the specification regarding priority. The objection to priority to US Application No. 08/844,419 (filed April 18, 1997) and 08/846,017 (filed April 25 1997) is not withdrawn, because these applications do not disclose the polynucleotide sequence that is identified as SEQ ID NO: 224 in the instant application.

2.2. Specification

Objection to the specification made in the previous Office Action is withdrawn, because the specification has been corrected.

2.3. Drawings

Formal drawings filed July 2, 2004 are acknowledged.

2.4. Claims

Objections to claims 1, 13 and 14 are withdrawn, because the claims have been corrected.

3. Rejections

3.1. 35 USC, section 112, second paragraph

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Rejection of claim 1 for lack of recitation of hybridization conditions made in the Office Action of Jan. 5, 2004, is withdrawn because the claim recites the hybridization conditions.

Claims 2-12 and 40 are rejected under this section because the base claim 2 recites the phrase "hybridizes specifically" which is indefinite without explicitly reciting the hybridization conditions.

Amended claims 2-12,14-19, 21 and new claim 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are directed to the use of **probe or primer that consists essentially of** a sequence identical or complementary to certain number of consecutive nucleotides of the encoding region of SEQ ID NO: 224.

In their Remarks filed with the Supplemental Response of May 17, 2004 Applicants, on page 13, line 3, define the meaning of the term **consisting essentially of** as follows:

"This means that the probe [consisting essentially of 25 or more consecutive nucleotides from hTRT encoding region of SEQ ID NO: 224] has 25 or more consecutive nucleotides SEQ ID NO: 224 (up to the full length of the hTRT encoding region), and may also have additional nucleotides, providing that the additional nucleotides do not substantially diminish the ability of the

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nucleotides taken from SEQ ID NO: 224 to hybridize a target nucleic acid in a specific fashion.”

This definition is vague because:

- 1) the term “substantially diminish” is a relative term for which Applicants do not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the term;
- 2) the probe is defined by hybridization to a target nucleic acid, which is to be selected by said probe. The probe should be identified by hybridization to the encoding region of SEQ ID NO: 224 or its fragment.
- 3) the hybridization conditions are not explicitly recited in the given definition.

On the same page, line 14, Applicants define the primer that **consists essentially of** a certain number of consecutive nucleotides from the hTRT encoding region of SEQ ID NO: 22 as follows:

“This means that each primer has 15 or more consecutive nucleotides of SEQ ID NO: 224, and may also have additional nucleotides, providing that the additional nucleotides do not substantially diminish the ability of the nucleotides taken from SEQ ID NO: 224 to specifically amplify a target hTRT nucleic acid.”

This definition is vague because:

- 1) the term “substantially diminish” is a relative term for which Applicants do not provide a standard for ascertaining the requisite degree, and one of

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ordinary skill in the art would not be reasonably apprised of the scope of the term;

- 2) the primer is defined by amplifying the target nucleic acid, which is to be selected by said amplification. The primer should be identified by amplifying the encoding region of SEQ ID NO: 224 or its fragment.

In the view of lack of clarity of the term "consisting essentially of" as defined by Applicants in their response of May 27, 2004, for examination purposes the term is considered to mean "comprising".

3.2. 35 USC, section 112, first paragraph

3.2.1. Lack of written description

Rejection withdrawal

Claims 1-22 were rejected in the Office Action of Jan 5, 2004. Rejection of claims 20 and 22 is moot because the claims have been canceled. Rejection of claims 1-19 is withdrawn because the claims have been amended.

2.2.2. Scope of enablement

In the view of lack of clarity of the term "consisting essentially of", see above in rejection under 35 USC, 112 second paragraph, claim 2-12,14-19, 21 and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the methods of using probes and primers consisting of the at least 25 or 15 consecutive nucleotides of SEQ ID NO: 224 (up to the full length of the hTRT encoding

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region), does not reasonably provide enablement for use of the primers and probes as claimed. The reasons are explained in the rejection in the Office Action of Jan. 5, 2004.

3.3. 35 USC section 103

In the interview Sept. 2, 2004, the examiner indicated the potential applicability of the paper by Linger, Huges, Shevchenko, Mann, Lundblad and Cech (Reverse Transcriptase Motifs in the Catalytic Subunit of Telomerase, Science, published April 25 (submitted March 4) 1997, 276/5312, pages 561-567) and Strausberg's sequence AA281296 entered to NBCI data base in April 2, 1997, in rejection under 35 USC section 103.

After reconsideration of

- 1) lack of priority of the instant application to the application US Application No. 08/844,419 (filed April 18, 1997), because 08/844,419 does not disclose SEQ ID NO:224 without which the instant invention is not described and enabled, and
- 2) the subject matter of the article,
the examiner considers the article is a prior art.

Claims 1-9, 12-19, 21 and 22- 37, 39-43 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strausberg's human sequence AA281296 entered to NBCI data base in April 2, 1997 in view of Linger, Huges, Shevchenko, Mann, Lundblad and Cech (Reverse Transcriptase Motifs in the Catalytic Subunit of

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Telomerase, Science, published April 25 (submitted March 4) 1997, 276/5312, pages 561-567).

The claims are directed to methods of identifying a nucleic acid that encodes human telomerase or a fragment thereof using probes or primers that hybridize to SEQ ID NO:224.

Strausberg discloses AA281296 human nucleotide sequence; the sequence is identical to nucleotides 1679-2067 of SEQ ID NO:224 (the alignment attached to the previous Office Action), however Strausberg does not teach that AA281296 can be used as a probe or primer in the method of identification of human telomerase by hybridization.

Linger et al. cloned *Euplotes aediculatus* and *Saccharomyces cerevisiae* telomerase reverse transcriptase and showed the highly homologous or conserved motifs (reverse transcriptase motifs and other motifs seen in Fig. 2 of the article). It would have been obvious for one of ordinary skill in the art to identify in a BLAST search conducted using *Euplotes* t123 kDA peptide and nucleic acid sequences, as well as *Saccharomyces* protein and corresponding cDNA, a homologous fragment of human origin which was partial cDNA clone having GeneBank accession #AA281296. It would also have been obvious to further use said partial cDNA clone to identify human telomerase encoding sequence as Applicants did (see Example 17, Cloning and Characterization of Human Telomerase Protein and cDNA, page 79 of the specification). The motivation was provided by Linger et al. who described on page 562 the use of BLAST search for cloning *S. cerevisiae* telomerase. The probability of

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success was very high, because using the BLAST search Linger et al., having Euplotes telomerase sequence, were able to clone and characterize *S. cerevisiae* telomerase. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claim 1–22 were rejected under 35 U.S.C. 103(a) in the Office Action of Jan. 5, 2004, as being unpatentable over Adams et al. homo sapiens cDNA sequence AA311750 (Initial assessment of human gene diversity and expression patterns based on 83 million nucleotides of cDNA sequence, Nature 377 (6547 Suppl), 3-174, 1995) in view of common knowledge in the field of molecular biology.

Rejection of claims 20 and 22 is moot because the claims have been canceled. Claims 1-9, 22 and 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. homo sapiens cDNA sequence AA311750 (Initial assessment of human gene diversity and expression patterns based on 83 million nucleotides of cDNA sequence, Nature 377 (6547 Suppl), 3-174, 1995) in view of the paper by Linger, Huges, Shevchenko, Mann, Lundblad and Cech (Reverse Transcriptase Motifs in the Catalytic Subunit of Telomerase, Science, published April 25 (submitted March 4) 1997, 276/5312, pages 561-567).

Adams et al. teach Homo sapiens cDNA 5' sequence identified as locus AA311750. This EST sequence is 258 nucleotides long, and exhibits 97.7% homology with the fragment of SEQ ID NO: 224 which consists of nucleotides 2649-2906. AA311750 comprises 164 nucleotide long, 20 nucleotide long, and 64 nucleotide long

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consecutive fragments of SEQ ID NO: 224; see sequence alignment attached to the previous Office Action. Adams et al. do not teach the use of AA311750 as probe/primer in identification of human telomerase.

Linger et al. cloned *Euplotes aediculatus* and *Saccharomyces cerevisiae* telomerase reverse transcriptase and show the highly homologous or conserved motifs (reverse transcriptase motifs and other motifs seen in the Fig. 2). It would have been obvious for one of ordinary skill in the art to identify in a BLAST search conducted using Euplotes 123 kDA peptide and nucleic acid sequences, as well as *Schizosaccharomyces* protein and corresponding cDNA (tez 1) a homologous fragments of human origin which was partial cDNA locus AA311750. It would also have been obvious to further use said partial cDNA clone to identify human telomerase encoding sequence. The motivation was provided by Linger et al. who described on page 562 use of BLAST search for finding *S. cerevisiae* telomerase. The probability of success was very high, and taught by Linger et al., because using the BLAST search Linger et al., having *Euplotes* telomerase sequence, were able to clone and characterize *S. cerevisiae* telomerase. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

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Applicants Remarks of Sept., 9, 2004 state that any rejection over the disclosure of Linger et al. would not be proper as Linger et al. is not prior art in view Applicants disclosure in US application 08/844,419 of both the *Euplotes* and *Saccharomyces* sequences as well as the motif analysis as disclosed in Linger et al. However, this is not persuasive as the benefit of the filing date of a priority application can only be granted if the prior application clearly describes and enables the entire subject matter of an examined claim. All of the currently rejected claims include subject matter (i.e. SEQ ID NO: 224) not supported by the disclosure of 08/844,419 and thus none of these claims can be granted the benefit of the filing date of the prior application. Applicants further suggest that the disclosure of Linger et al. is a publication by inventors and this is not "by other". However, the Linger et al. reference is by Linger, Huges, Shevchenko, Mann, Lundblad and Cech, while the invention entity of the instant application is Linger, Nakamura, Morin, Harley and Andrews. As such Linger et al. article is clearly "by other". Furthermore, any showing that the Linger et al. reference is a disclosure of Applicants' own invention must be made in a 1.132 declaration. No such declaration has been provided.

4. Conclusion

Claims 10-11 and 38 and 42 are free of prior art. No claim is in condition for allowance, however the claim contained allowable subject matter. The following is the examiner reason for indicating the allowable subject matter. Applicants are the first to

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disclose human telomerase. The claimed invention is of great importance in diagnostics and potentially in therapy of human disorders such as cancer and aging.


As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-1600. The fax phone number for this Group is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 872-9306.

Malgorzata A. Walicka, Ph.D.

Patent Examiner

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REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800-
1652